

REMARKS

By this amendment claims 102, 103 and 141 have been amended, claims 145-149, 151-175, and 179-181 have been canceled and new claims 183 and 184 have been added. Accordingly, claims 102-107, 109-112, 114-133, 137-139, 141, 142, 183 and 184 are pending in this application. No new matter has been introduced by this Amendment.

In the Office Action dated March 7, 2007, claims 102-108, 114-118, 120-127, 130, 131, 133, 137-139, 141, 142, 145-149, 156-160, 162-169, 172, 173, 175, and 179-181 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Nos. 5,411,520 or 5,312,435 to Nash. In addition, claims 102, 112, 132, 141, 154, and 174 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,707,150 to Montgomery et al. Further, claims 102, 112, 131, 132, 141, 154, 173, and 174 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,493,898 to Woods et al. Still further, claims 109-111, 119-124, 128, 129, 151-153, 161-166, 170, and 171 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Nash in view of U.S. Patent No. 5,904,703 to Gilson, U.S. Patent No. 6,224,630 to Bao et al., or U.S. Patent No. 5,733,337 to Carr, Jr. et al.

Rejections under 35 U.S.C. § 102(b) based on Nash

The Examiner refers to two patents to Nash in the outstanding rejection, namely U.S. 5,411,520 and 5,312,435. Anticipation under §102(b) requires all elements of the claim to be found in a single reference. See *MPEP* § 706.02(IV).¹ Accordingly, in the

¹ "Under [35 U.S.C. 102], the claim is anticipated by the reference. No question of obviousness is present. In other words, for anticipation under 35 U.S.C. 102, the reference must teach every aspect of
(continued...)"

interest of providing a complete response, each Nash reference will be treated separately on its own merits.

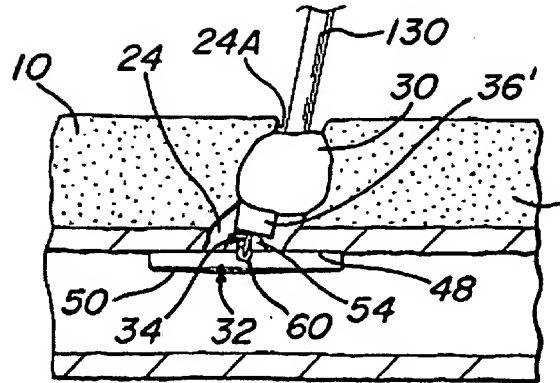
U.S. 5,411,520 to Nash

Claims 102-108, 114-118, 120-127, 130, 131, 133, 137-139, 141, 142, 145-149, 156-160, 162-169, 172, 173, 175, and 179-181 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,411,520 to Nash ("Nash '520"). Claims 145-149, 156-160, 162-169, 172, 173, 175, and 179-181 have been canceled. Therefore, claims 102-108, 114-118, 120-127, 130, 131, 133, 137-139, 141, 142 will be addressed here. Claim 141 has been amended into dependent form, and now depends from claim 102, which is the only remaining independent claim.

As amended, claim 102 recites, among other things, a fixation element that passes into or through said tissue surrounding said aperture. Nash '520 does not disclose or suggest this element, nor does Nash disclose any structure capable of such use. Nash '520 is concerned with hemostatic closure, which when *in situ* prevents the flow of blood from a vessel. Figure 27 of Nash '520 depicts the closure after introduction and deployment:

(...continued)

the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present."



As disclosed, the closure comprises an anchor (32) which is placed below the puncture (24) in the vessel. The puncture (24) through the vessel is located at the end of tract (24A) formed through tissue (10). The anchor (32) is placed using tamping member (130), and is held proximate the puncture (24) by filament (34), which passes through opening (60) of the tamping member (130). The actual hemostatic seal is created by plug member (30), which is held in the tract (24A) and tethered to anchor (32) via filament (34). See generally col. 14, ll. 10-36.

The filament (34) does not pass into or through the tissue surrounding the puncture (24):

The manner of connection of the plug member to the anchor member will be described later. Suffice it for now to state that the filament 34 of the closure device 22 serves to couple the plug component to the anchor component in an arrangement to effect the movement of the plug component toward the anchor component, once the anchor component is in its desired position in the artery at the puncture or incision. In particular the coupling of the plug component to the anchor component simulates a pulley to achieve a desired mechanical advantage.

Nash '520, col. 7, l. 60 to col. 8, l. 2 (emphasis added). Clearly, this pulley-like, mechanical tensioning of the filament does not disclose, suggest, permit, or otherwise

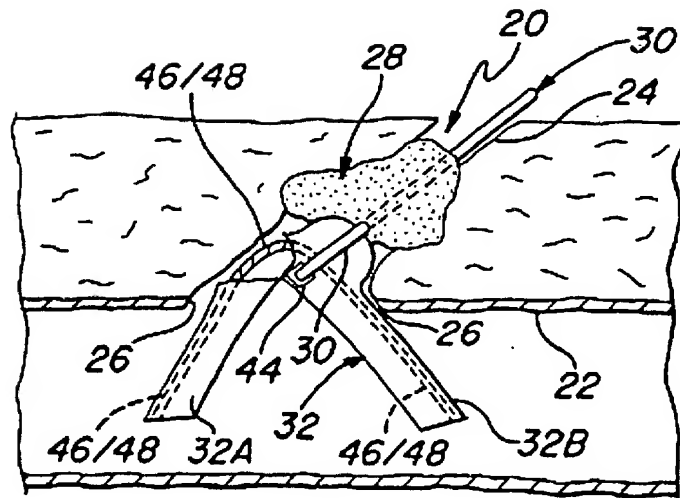
allow passing the filament into or through tissue surrounding an aperture, as set forth in claim 102.

It is therefore respectfully submitted that Nash '520 cannot anticipate claim 102 for at least the reasons set forth above. All other claims depend from claim 102, and are therefore not anticipated for the same reasons. It is therefore respectfully requested that the rejection be withdrawn.

U.S. 5,312,435 to Nash

Claims 102-108, 114-118, 120-127, 130, 131, 133, 137-139, 141, 142, 145-149, 156-160, 162-169, 172, 173, 175, and 179-181 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,312,435 to Nash ("Nash '435"). As set forth above, claims 145-149, 156-160, 162-169, 172, 173, 175, and 179-181 have been canceled. Therefore, claims 102-108, 114-118, 120-127, 130, 131, 133, 137-139, 141, 142 will be addressed here. Also as set forth above, Claim 141 has been amended into dependent form, and now depends from claim 102, which is the only remaining independent claim.

As amended, claim 102 recites, among other things, a fixation element that passes into or through said tissue surrounding said aperture. Nash '435 does not disclose or suggest this element, nor does Nash disclose any structure capable of such use. Nash '435 is concerned with hemostatic closure, which when *in situ* prevents the flow of blood from a vessel. Figure 5 of Nash '435, reproduced below, depicts the closure after introduction and deployment, and during removal after the anchor is broken:



As disclosed, the closure comprises an anchor (32) which is placed below the opening (26) in the vessel. The opening (26) through the vessel (22) is located at the end of tract (24) formed through tissue. The anchor (32) is held proximate the opening (26) by filament (30). The actual hemostatic seal is created by plug sealing member (28) who is held in the tract (24), and tethered to anchor (32) via filament (34). See, generally, col. 3, ll. 45-62.

The filament (30) does not pass into or through said tissue surrounding the opening (26):

The filament connects the anchor member and the collagen plug (sealing member) via a pulley-like arrangement which serves to move the plug toward the anchor member by pulling on the filament when that member is located within the interior of the artery and in engagement with the inner wall of the artery contiguous with the incision or puncture.

Nash '520, col. 7, l. 60 to col. 8, l. 2 (emphasis added). Clearly, this pulley-like, mechanical tensioning of the filament does not disclose, suggest, permit, or otherwise allow passing the filament into or through tissue surrounding an aperture, as set forth in

claim 102. Indeed, the primary concern of Nash '435 is the retrievability of a broken anchor from the vessel, to avoid embolism. See col. 1, l. 68 et seq. Clearly this concern is inapposite to suturing the device *in situ*.

It is therefore respectfully submitted that Nash '435 cannot anticipate claim 102 for at least the reasons set forth above. All other claims depend from claim 102, and are therefore not anticipated for the same reasons. It is therefore respectfully requested that the rejection be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 109-111, 119-124, 128, 129, 151-153, 161-166, 170 and 171 were rejected under 35 U.S.C. § 103(a) as being unpatentable over either Nash '520 or Nash '435 in view of Gilson (U.S. 5,904,703), Bao et al. (U.S. 6,224,630) or Carr, Jr. et al. (U.S. 5,733,337). As set forth above, claims 151-153, 161-166, 170 and 171 have been canceled. Therefore, claims 109-111, 119-124, 128 and 129 will be addressed here.

The official action relies on Gilson, Bao and Carr, Jr. for specific features. Specifically, Gilson and Bao are relied upon for teaching a compressible, porous, polymeric foam; and Carr, Jr. for teaching a tissue repair fabric. None of these references were relied upon to address the central deficiency of the primary Nash references, namely a fixation element passed into or through tissue surrounding an aperture, in combination with the other claimed features. Accordingly, these references do not rehabilitate the Nash references, nor render the claims obvious for the same reasons set forth above with respect to either Nash '520 or Nash '435.

It is therefore respectfully submitted that none of the cited references, alone or in combination, render claim 102 obvious for at least the reasons set forth above. All other

claims depend from claim 102, and are therefore not obvious for the same reasons. It is therefore respectfully requested that the rejection be withdrawn.

Rejections under 35 U.S.C. § 102(b) based on Montgomery

Claims 102, 112, 132, 141, 154, and 174 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,707,150 to Montgomery. Claims 154 and 174 have been canceled. Therefore, claims 102, 112 and 132 will be addressed here. Claim 141 has been amended into dependent form, and now depends from claim 102, which is the only remaining independent claim.

As amended, claim 102 recites, among other things, a device that comprises material capable of tissue ingrowth. Montgomery does not disclose or suggest this element, nor does Montgomery disclose any structure capable of such use. Montgomery is concerned with treating anterior glottic stenosis by providing a laryngeal keel, which when *in situ* enhances re-epithelialization after removal of granulated tissue. Using a laryngeal keel helps prevent recurrence of the stenosis by promoting the formation of naturally-occurring epithelial cells over the tissue where stenotic or other tissue was removed. The keel is removed after a period of weeks, and is specifically not designed for tissue ingrowth. Indeed, tissue ingrowth would not allow removal of the keel and would lead to not insubstantial trauma to the region if this to be attempted, contrary to the goals articulated by Montgomery (*i.e.*, healing). Of course, keels such as Montgomery's would not be designed to be ingrown, because their very purpose is to promote even healing of tissue in the place of removed stenotic tissue.

For the above reasons, it is respectfully submitted that Montgomery does not disclose a material capable of tissue ingrowth. For at least this reason, Montgomery

does not anticipate claim 102. All other claims depend from claim 102, and are therefore not anticipated for the same reasons. It is therefore respectfully requested that the rejection be withdrawn.

Rejections under 35 U.S.C. § 102(e) based on Woods

Claims 102, 112, 131, 132, 141, 154, 173, and 174 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,493,898 to Woods et al. Claims 154, 173, and 174 have been canceled. Therefore, claims 102, 112, 131, 132, and 141 will be addressed here. Claim 141 has been amended into dependent form, and now depends from claim 102, which is the only remaining independent claim.

Woods discloses an applicator, such as that used for shoe polish. Woods does not disclose a material capable of tissue ingrowth, nor a fixation element that passes into or through said tissue surrounding an aperture. For these reasons, as discussed in more detail with respect to the rejections above, Woods does not anticipate claim 102. All other claims depend from claim 102, and are therefore not anticipated for the same reasons. It is therefore respectfully requested that the rejection be withdrawn.

Conclusion

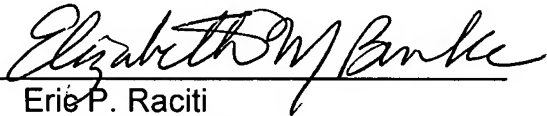
In view of the foregoing remarks, Applicant respectfully requests the reconsideration and reexamination of this application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account no. 06-0916.

Respectfully submitted,

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